

PRESENTS

Hot Topics in Pharmaceutical Microbiology:

Pharmig's 17TH Annual Irish Conference



PLUS, a one-day meeting covering Best Practices in Environmental Monitoring

Dublin (Portmarnock Hotel)

22ND May 2024: Annual One-Day Conference

23RD May 2024: Best Practices in Environmental Monitoring Meeting

Pharmig are excited to announce for the conference we have secured

Overview and future plans for USP microbiological standards

Marsha Steed - Expert in Sterility Assurance,

Founder and President - Steed MicroBio LLC & USP Microbiology Expert Committee Member

The HPRA addresses sterilisation

Ciara Turley - Senior GMP Inspector, HPRA

Plus leading industry experts will be covering key hot topics including

- Vision of Annex 1 updates and the reality of what has now been implemented
- Building a new micro lab
- Method suitability for non-steriles
- Rapid microbiology testing: automated readout of culture media

Best Practices in Environmental Monitoring Meeting

Will consist of lecture-led presentations, a group exercise, and an in-depth panel discussion session on Contamination control strategy and how to use environmental monitoring to manage contamination risks to round off the day

Take a look inside for more detailed information on both events.

EARLY BIRD OFFER: Send 2 or more people for

Send 2 or more people from the same site & discounts will apply until:

Friday 12TH April

(See booking form for more information)

HOT TOPICS IN PHARMACEUTICAL MICROBIOLOGY

PHARMIG'S 17TH ANNUAL IRISH CONFERENCE - 22ND MAY 2024

09.00 - 09.30

Registration

09.30 - 09.40

Chairs Welcome

Dr. Tim Sandle – Head of GxP Compliance, Sterility Assurance & Quality Risk Management, BPL and Pharmig Committee

09.40 - 10.20

Overview and future plans for USP microbiological standards

Marsha Steed – Expert in Sterility Assurance, Founder and President – Steed MicroBio LLC & USP Microbiology Expert Committee Member

10.20 – 11.00

Cytiva's gloveless robotic isolator system: case study

To reduce the risk of contamination, barrier systems have progressively reduced the amount of human intervention in the critical zone, typically through the use of gloves. The operator is acknowledged as the greatest potential source of contamination in aseptic processing, yet interventions have historically been an integral part of the aseptic process. However, the "perfect" intervention is the one that never occurs. This study analyses the critical design elements and performance of the Cytiva SA25 Aseptic Filling Workcell that enables increased product and patient safety by eliminating operator interventions into the critical zone.

Aine Brennan, Technical & Regulatory Leader, Aseptic Filling & Microbiologist, Cytiva

11.00 – 11.30

Meet & greet the exhibitors with tea/coffee

11.30 – 12.10

Rapid microbiology testing automated readout of culture media

Microbiology in the pharmaceutical industry is used for more than 100 years, however, rapid methods are much more recent. Several fields are concerned: Research and development, Bioburden, Sterility testing and Environmental monitoring. Rapid methods represent a large variety of modifications regarding the traditional culture method: composition of the medium (chromogenic), format (liquid, solid, cartridge...), incubation conditions (automated, time, temperature), reading (use of automatic readers). This presentation will focus on the available methods and trends for automatic readout of culture media, their advantages, and limitations.

Peter Penn – Director, NaughtonPenn Consultants

12.10 – 12.50

HPRA addresses sterilisation

Ciara Turley - Senior GMP Inspector, HPRA

12.50 - 14.00

Lunch in the exhibition area

14.00 - 14.40

Open discussion sessions

The aim of these sessions is to encourage discussion, share issues, solutions and experiences in a smaller, more informal environment helping you to benchmark against otherdelegates/companies.

Go to page 3 to view open discussion sessions

14.40 - 15.10

Open discussion sessions

The aim of these sessions is to encourage discussion, share issues, solutions and experiences in a smaller, more informal environment helping you to benchmark against otherdelegates/companies.

Go to page 3 to view open discussion sessions

15.10 – 15.30

Meet & greet the exhibitors with tea/ coffee

15.30 – 16.10

Method suitability for non-steriles

- The basics
- Common issues, challenges and how to overcome them
- Challenging test matrices
- Method transfer, variability considerations
- Hints & tips

Miriam Guest – Senior Principal Scientific Advisor, Charles River Laboratories

16.10 – 16.40

Vision of Annex 1 updates and the reality of what has now been implemented

Aisling Bonner Associate Director, Abbvie

16.40 – 17.00

Panel discussion, additional questions and close of Conference

HOT TOPICS IN PHARMACEUTICAL MICROBIOLOGY

PHARMIG'S 17TH ANNUAL IRISH CONFERENCE - 22ND MAY 2024

OPEN DISCUSSION SESSIONS

The aim of these sessions is to encourage discussion, share issues, solutions and experiences in a smaller, more informal environment helping you to benchmark against other delegates/companies.

Please tick 2 out of the 3 listed below on your booking form (page 6)

A) CCS and Annex 1

As you know EU GMP Annex 1 requires each facility to have in place a contamination control strategy (CCS) covering microbiological, particulate and chemical risks..

Come and discuss with your peers in an informal gathering:

- How companies have designed and set up their CCS; where do approaches differ?
- How has implementation gone so far. What are the variances between companies and where are the gaps?
- Where do we go from here?

Led by: Patrick Nieuwenhuizen (Cencora PharmaLex)

B) Non-Sterile open surgery

The sterile pharmaceutical sector has a well-defined set of expectations and regulations which provide clear statements relating to microbiological controls and monitoring. In contrast, the expectations for non-sterile pharmaceuticals are poorly defined, with few specifics written in either legislation or guidance publications.

Join this informal open surgery to ask questions, benchmark, find out how others have solved problems and delt with challenges in non-sterile product manufacturing. Topics may include microbial identification, objectionable organisms, risk assessment, or anything else that's challenging you at the moment.

Led by: Edel Fitzmaurice (Pharmig)

C) Sterile open surgery

Sterile manufacturing continues to be challenging. The past few years have seen the implementation of the new EU GMP Annex 1, the requirement for facilities to develop a detailed contamination control strategy, and the range of sterilisation technologies that vendors are using to supply materials is expanding fast.

Whether your questions are about sterilisation methods, environmental monitoring, water system controls, bioburden testing, or the overall strategy, please drop in and share your experiences with other delegates and the Pharmig committee.

Led by: Tim Sandle (Pharmig)

Please note: All information addressed by the speakers are of their own / company opinions. Pharmig is not responsible for any content presented at the meeting.

Pharmig also has the right to change the programme at any time due to unforeseen circumstances.



BEST PRACTICES IN ENVIRONMENTAL MONITORING (EM)

23RD MAY 2024

09.00 - 09.30

Registration with tea/coffee

09.30 - 09.40

Chairs Welcome

Dr. Tim Sandle – Head of GxP Compliance, Sterility Assurance & Quality Risk Management, BPL and Pharmig Committee

09.40 - 10.20

Highlighting what Annex 1 is describing regarding environmental monitoring – setting the scene

Annex 1 has a full section dedicated to Environmental and Process Monitoring. It covers 6 pages and provides guidance on the expectations of the design of an EM program, types of sampling to apply and expected limits per classification and how to follow up on excursions. This session will give a broad overview of Section 9 of Annex 1 and what to account for before taking a deeper dive of each topic in the individual presentations throughout the day.

Patrick Nieuwenhuizen – Director, Principal Consultant, Cencora PharmaLex

10.20 – 11.00

Back to basics: What the environmental monitoring programme needs to contain

Marsha Steed – Expert in Sterility Assurance, Founder and President – Steed MicroBio LLC & USP Microbiology Expert Committee Member

11.00 – 11.30

Mingle with exhibitors over tea & coffee

11.30 – 12.10

Knowing your microflora and understanding the sources of contamination in your environment

- When to identify?
- How to Identify?
- What your identifications can tell you about the sources of contamination in your environment
- When do you need to take action?

Edel Fitzmaurice – Quality Director, QP, Fitzmaurice Scientific Ltd

12.10 – 13.10

Lunch

13.10 - 13.50

What to do with environmental monitoring data?

- Why trend analysis is important?
- How to summarise data
- How to deal with microbial counts and data trending

- How to deal with contamination frequencies and data trending
- How to profile microbial contamination and look for patterns
- How to summarise the status of different areas
- What does a good report look like?

Monica Di Matta - Quality Risk Manager, BPL & Joanna Wolodkowicz - Contamination Control Manager, BPL

13.50 - 14.00

Investigating environmental monitoring

This presentation looks at the main steps involved for conducting investigations and provides some best practice advice for the company microbiologist. Among the topics covered:

- Limitation of microbial data
- Assessing the validity of microbiological tests
- Evidence gathering
- Trending
- Getting into the plant
- Measuring effectiveness
- Case studies

Dr. Tim Sandle – Head of GxP Compliance, Sterility Assurance & Quality Risk Management, BPL

14.00 - 14.20

Tea & coffee with the exhibitors

14.20 – 15.20

Risk based approach to setting environmental monitoring locations

- Introduction to risk-based approaches.
- Assessing contamination sources and sample types.
- Importance of selecting meaningful locations.
- The effective use of HACCP methodology.
- Group exercise:

Analysing a pharmaceutical process area to select appropriate environmental monitoring locations by understanding product and people flows

Monica Di Matta - Quality Risk Manager, BPL & Joanna Wolodkowicz - Contamination Control Manager, BPL

15.20 – 16.20

Contamination control strategy panel discussion – how to use environmental monitoring to manage contamination risks

Tim Sandle, Edel Fitzmaurice, Patrick Nieuwenhuizen, Monica Di Matta, Joanna Wolodkowi, Marsha Steed

16.20 – 16.30

Closing remarks and end of meeting

PRICING / BOOKING FORMS / PAYMENT DETAILS

DISCOUNTED OFFERS for sending 2 or more delegates ends on Friday 12th April 2024

INFORMATION ON FEES & PAYMENTS

- Please tick the relevant meeting fee(s) and dates outlined in Booking Form A, B or C below
- You will need to send pages 5 & 6 back to Pharmig to register your booking

	FORM A CO DLOGY 22 ND N		ICE: HOT TOPICS	S IN PHARMAC	CEUTICAL	
_	people from the same s 2024. Please tick releva		e a discount on the full 1st at w	ttendee rate as outlined	d below until	
MEMBER FEES	EURO/STERLING		NON-MEMBER FEES	EURO/STERLING		
1ST MEMBER 2ND MEMBER	€705/ £595 €588 / £495		1ST NON-MEMBER 2ND NON-MEMBER	€822/ £695 €705/ £595		
MONITOR Send 2 or more p	ING 23RD MAY	ite and receive	FICES IN ENVIROR The a discount on the full 1st at		l below until	
MEMBER FEES	EURO/STERLING		NON-MEMBER FEES	EURO/STERLING		
1ST MEMBER	€588/ £495		1ST NON-MEMBER	€822/ £695		
2ND MEMBER	€471 / £395		2ND NON-MEMBER	€705/ £595		
BOOKING FORM C BOOKING BOTH THE ONE-DAY CONFERENCE & BEST PRACTICES IN ENVIRONMENTAL MONITORING 22 ND & 23 RD MAY If you wish to attend both meetings – further discounted fees are as follows: Please tick relevant boxes below						
MEMBER FEES	EURO/STERLING		NON-MEMBER FEES	EURO/STERLING		
1ST MEMBER	€1283/ £1090		1ST NON-MEMBER	€1575/ £1340		
2ND MEMBER	€991/ £840		2ND NON-MEMBER	€1400 / £1190		

NOTE: *Euro fee is higher to cover conversion rates

FEES INCLUDE (If attending in-person): lunch/ refreshments on the day and a link to download presentations in advance of the meeting(s). **Conference fees do not include accommodation**, which must be booked and paid for directly with the hotel.

REGISTRATION & PAYMENT INFORMATION

Please reserve place(s) for the Pharmig Annual Irish Conference and Best Practic the 22nd & 23rd May – Portmarnock Hotel, Dublin	ces in Environmental Monitoring running on		
Company:			
Address :			
Contact name (if different from the delegate):			
 Please complete the relevant booking sections below - in person Please tick dates attending / Please complete the payment section on the next Please send back pages 5 & 6 when booking 	t page		
IN PERSON ATTENDANCE TICK REQUIRED DATES CONF DAY 22ND	MAY EM DAY 23RD MAY		
1 st Delegate Name:	OPEN DISCUSSION SESSIONS Please tick TWO sessions you wish to attend		
*Email:	A) CCS and Annex 1		
Job Title:	B) Non-Sterile open surgery		
Dietary requirements:			
	C) Sterile open surgery		
IN PERSON ATTENDANCE ZND Delegate Name:	OPEN DISCUSSION SESSIONS Please tick TWO sessions you wish to attend		
*Email:			
	A) CCS and Annex 1		
Job Title:	B) Non-Sterile open surgery		
Dietary requirements:	C) Sterile open surgery		
METHODS OF PAYMENT Email or fax your completed booking form for a confirmed place: Email: info@pharmig.org.uk Fax: to +44 (0) 1920 871 156 Please tick the relevant box below Please raise an invoice to cover the delegate fee(s) f/€ UK BACS Sort code: 60 19 28 Account: 80843867 f/€			
Wire Transfer: Natwest Bank, 118 High Street, Slough, Berkshire SL1 1JH £/€ SWIFT (BIC) NWB KGB2L Account: 80843867 IBAN GB64 NWBK 6019 2880 843 867 Please quote company approved purchase order no £/€			

VENUE INFORMATION

DUBLIN

THE VENUE

Portmarnock Hotel. – 10miles to the north of Dublin City and a 15-minute drive from Doublin Airport from Dublin Airport with good road access to Cork. The hotel has full conference facilities with accommodation, dining choices and spa area.

ACCOMMODATION

A limited number of bedrooms have been reserved at a special rate of €185 (B&B single occupancy) for overnight delegates (please book early to avoid disappointment).

Rooms need to be booked directly with the hotel.

Please call The Portmarnock Hotel & Golf Links on + 353 (0) 1 846 0611 – and quote Pharmig to ensure you receive the discounted rate.

ADDRESS: Portmarnock Hotel & Golf Links, Strand Road, Portmarnock, Co. Dublin, Ireland



CANCELLATION POLICY

Written cancellation will be accepted up to 30 days prior to the event, and all cancellations will incur a fee. No refunds are available 15 working days before the start date and full course fees will be due for delegates who fail to attend. Substitutions may be made at any time, preferably in writing to Maxine Moorey.

PRIVACY POLICY

By registering for these events, I accept the processing of my Personal Data. Pharmig will use my data for the processing of this order for which I hereby declare to agree that my personal data is stored and processed. Pharmig will only send information in relation to this order or similar events/publications/training courses etc. Pharmig may send your name and company only to other companies attending the same event in the form of an attendee list.

Your full personal data will not be disclosed to third parties. See also privacy policy at https://www.pharmig.org.uk/en/privacy-policy/.

You can ask for the modification, correction or deletion of your data at any time via an email to maxine@pharmig.org.uk

Pharmig Publications, Fact Sheets & Online Training Modules

Pharmig publications, fact sheets, and on-line training modules have been written and produced by industry leaders. They contain and cover key information relating to GMP standards and regulations.

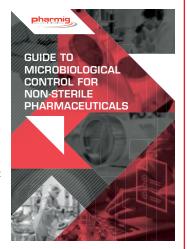
Publication orders can be placed via the website - www.pharmig.org.uk

Guide to microbiological control for Non-Sterile <u>pharmaceuticals</u>

This Guide is relevant to non-sterile pharmaceutical, cosmetic and toiletry manufacturing industries. There have been significant changes in the microbiological regulations, controls, and testing of non-sterile products. Much of the changes has been prompted by the many recalls of nonsterile products worldwide.

- · Microbiological testing and data handling
- Facility and equipment design
- Objectionable microorganisms
- Cleaning & disinfection
- Risk assessment & data management
- Environmental monitoring
- Regulatory expectations for nonsterile manufacture

Member £80 Non Member £110



Cleaning and disinfection of pharmaceutical facilities - a road map to regulatory compliance

The guide has been completely revised and re-written to provide you with a roadmap to regulatory compliance for cleaning & disinfection. The new text will walk you through the steps needed to design, validate, and implement an effective cleaning and disinfection programme. Including:

- Identifying and assessing risks associated with cleaning and disinfection
- User requirements for cleaning agents and disinfectants
- Supplier qualification
- Disinfectant efficacy testing and validation
- Controls for routine use including application methods. in-coming QC testing, and periodic review of the programme

Member £60 Non Member £85



Best practices for the bacterial endotoxin test: A guide to the LAL assay

This guide to the Bacterial Endotoxin Test (BET) provides the reader with an overview of the history, regulation and practical use of the different BET assays. Information on method development, validation and routine testing are discussed as well as more advanced subjects such as depyrogenation, medical devices, trouble shooting and problem samples

The guide should provide a useful reference document for LAL users and laboratory management.

Member £50 Non Member £75



Guide to cleanroom operation and <u>contamination control</u>

This publication provides a short and informative introductory guide to cleanrooms. Cleanrooms provide controlled, critical environments for both sterile and non-sterile pharmaceutical manufacturing.

The guide examines:

- Cleanrooms
- · Different grades of cleanrooms
- The important aspects of physical control
- Contamination control and environmental monitoring
- Important cleanroom parameters

required by the regulatory standards

Member £60 Non Member £85





T: + 44 (0) 1920 871 999

E: info@pharmig.org.uk

F: +44 (0) 1920 871 156 W: www.pharmig.org.uk



Guide to microbiology laboratories in the pharmaceutical industry

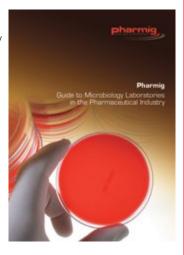
This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries

The Guide describes considerations to be applied to the design, set up and running of the microbiology unit.

Topics range from:

- Test methods
- · Environmental monitoring
- Documentation
- · Method verification and validation

Member £60 Non Member £85



<u>Current perspectives on environmental</u> <u>monitoring - Review # 1</u>

This review surveys some of the current practices, trends and approaches to environmental monitoring.

Technical articles include:

- Constructing an environmental monitoring programme
- Particle monitoring & control
- Environmental monitoring & risk assessment
- Microbiological risk assessment case study

Member **£60**Non Member **£85**



Rapid & alternative microbiological methods

Rapid Microbiological Method technologies aim to provide more sensitive, accurate, precise and reproducible test results when compared with conventional, growth-based methods. They normally involve some form of automation and they often capture data electronically.

Microbiologists can be inundated with literature advertising equipment and courses relating to 'Rapid Microbiological Methods' and 'Alternative Microbiological Methods'.

Whilst costs cannot be discussed, this document has been prepared:

- to describe the range of well developed, established, commercially available methods and their suitability for evaluating the microbiological quality of products or raw materials;
- to provide some guidance for microbiologists who are investigating the use of R/AMM in routine quality control of cosmetics personal care products and pharmaceuticals.

Member £20 Non Member £35



Guide to bacterial identification

Microbial identification represents an important part of the microbiology function. This includes screening products for objectionable organisms, profiling the environmental microbiota, and investigating out-of-limits events with a view to assigning a probable point of origin. In deciding what and when (and subsequently to what level) to identify, and by the way of which methods, requires an identification strategy. This is a document each microbiology laboratory should develop.

During a Pharmig presentation on microbial identification strategy and a Q&A session that followed there was a variation in approach, and sometimes a lack of clarity, concerning good identification practices and in outlining a strategy of what to identify and when. To provide guidance for members and other microbiologists, in the way of a training aid, and to provide the basis for microbiology laboratories to benchmark against, this guide was put together.



Chapters within the Guide include:

- Cleanrooms
- Different grades of cleanrooms
- The important aspects of physical control
- Contamination control and environmental monitoring
- Important cleanroom parameters required by the regulatory standards

Member £60

Non Member £85



Commonly Occurring Organisms -Pharmig's latest series of 8 fact sheets

This series of 8 fact sheets will cover:

- Dermacoccus nishinomiyaensis
- Corvnebacterium
- tuberculostearicum
- Cutibacterium acnes
- Micrococcus luteus

Member £30 Non Member £50

- Kocuria rhizophila
- Staphylococcus hominis
- Paenibacillus glucanolyticus
- Microbacterium liquefaciens



A series of 8 Water Microbiota **Fact Sheets**

This series of 8 fact sheets will cover:

- Ralstonia pickettii
- Stenotrophomonas maltophilia
- Burkholderia cepacia complex
- Acinetobacter baumannii
- Brevundimonas diminuta

Member £30 Non Member £50

- Sphingomonas paucimobilis
- Pseudomonas aeruginosa
- General overview of water microorganisms



LAL Fact Sheets

A series of Limulus Amoebocyte Lysate (LAL) laminated Fact Sheets on pyrogen/ endotoxin testing have been produced by the LAL Action Group. The series of 6 LAL fact sheets (as a package)

currently available are:

- What is LAL/BET?
- · Calculation of **Endotoxon Limits**
- Medical Devices
- Gel Clot Methods Photometric Methods
- **Product Validations** Quantitative Methods

Member £20 Non Member £35



A series of 8 Microorganisms Fact Sheets

The microbial enumeration test and test for specified microorganisms can represent a challenging area for pharmaceutical microbiology. To act as a training aid for new staff, and an aide memoire for more experienced staff - Pharmig has produced eight fact sheets. Seven of the fact sheets profile each one of the

key microorganisms (or microbial groups), using colour photographs illustrating growth on agar and by Gram-stain. These are supported by facts relating to the organism's profile and methods for identification. The eighth sheet offers some useful guidance about the interpretation of the test.

Member £30 Non Member £50



A series of 8 Major Objectionable **Microorganisms Fact Sheets**

One of the expectations of GMP regulators is that microbiology laboratories are knowledgeable about the main objectionable microorganisms that could be found in pharmaceutical products or in the manufacturing environment. The identification, characterisation and interpretation of these microorganisms can be challenging. To act as a training aid and information resource. Pharmig has produced eight new fact sheets (Fact Sheet Pack 2). Seven of

the fact sheets profile some of the most important objectionable microorganisms (together with Geobacillus stearothermophilus, used for biological indicators). An eighth fact sheet provides useful information about risk assessing objectionable microbes.

Member £30 Non Member £50



A series of 8 Pharmaceutically Important **Fungi Fact Sheets**

This set of fact sheets features seven fungi which feature high in causes of fungal contamination of pharmaceutical products and which have led to several major pharmaceutical product recalls. Each fact sheet presents information about the fungus, including growth conditions and product / patient risks. Each sheet details a striking photograph of the fungus macroscopically,

growing on suitable agar, and microscopically (as a methylene blue stain.) The eighth fact sheet is a guide on the staining and microscopic examination of fungi, including

key features to note to help you with identification. The fact sheets are laminated, making them suitable for the laboratory bench, and come enclosed within a presentation folder

Member £30 Non Member £50



For more information contact

T: + 44 (0) 1920 871 999

E: info@pharmig.org.uk

F: +44 (0) 1920 871 156 W: www.pharmig.org.uk



Pharmig's Interactive Online Training Modules

The Pharmig Training Portal can be used via a stand-alone log-on, or integrated into your electronic learning management system.

The Pharmig Training Portal gives your team access to high quality online training.

By watching a series of detailed videos, followed by a multiplechoice assessment, they will learn about essential subjects relating to their working environment. On successful completion of a module, participants will be issued with a certificate of completion.

Personnel training made easy, quantifiable and interactive. These training modules are aimed at those who are new to working in GMP cleanrooms including production, cleaning, QA, QC and engineering staff.



Module 1: Cleaning & Disinfection of Cleanrooms

Module Chapters Include:

- Introduction to contamination in cleanrooms
- Preparation and storage of cleaning agents and disinfectant
- Application Techniques

3

Module 2: Gowning for Non-sterile Facilities

Module Chapters Include:

- The importance of personal hygiene
- Hand hygiene washing, disinfection, gloving
- Gowning for non-sterile areas
- Gowning for laboratory areas
- Garment laundering

Module 3: Gowning for Sterile Facilities

Module Chapters Include:

- The importance of personal hygiene
- Hand hygiene washing, disinfection, gloving
- Gowning for non-sterile areas
- Gowning for sterile areas

- Gowning for laboratory areas
- Gowning qualification
- Garment laundering and sterilisation

More detailed information regarding each module chapters and learning can be found at: www.pharmig.org.uk/en/products/online-training



PLEASE DO FOLLOW US ON...

@pharmig_group

Pharmig (Excellence in Microbiology)







Pharmig Microbiology



Pharmig (Excellence in Microbiology)